K 130307

MAR 0 4 2013

510(k) Summary of Safety and Effectiveness

Summary Date: February 5, 2013

Submitter: CeloNova BioSciences, Inc.
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San Antonio, TX 78258
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Contact : Nicole C. Barber
Sr. Regulatory Specialist

1. Common name, Trade name & Classification

Trade Name: ONCOZENE™ Microspheres

Common Name & Codes: Vascular Embolization device, embolization, arterial (21CFR 870.3300, product code KRD)

2. 510(k) Number and Product code of predicate device

Trade Name: Embozene Microspheres

Manufacturer: CeloNova BioSciences, Inc.

510(k) number: K073417

Product code : KRD, 21 CFR 870.3300

3. Indications for Use and Intended Purpose

ONCOZENE™ Microspheres are intended for embolization of hypervascular tumors and arteriovenous malformations.

4. Device Description

ONCOZENE™ Microspheres are precise dimensioned, soft, deformable microspheres intended to occlude vasculature for the purpose of blocking blood flow to a target tissue such as hypervascular tumor (HVT) or arteriovenous malformation (AVM). ONCOZENE™ Microspheres are manufactured from sodium polymethacrylate and coated with proprietary Polyzene®-F. The fully polymerized microspheres are compressible to enable smooth delivery through the indicated delivery catheter. ONCOZENE™ Microspheres contain no added dyes and are visually opaque.

ONCOZENE™ Microspheres are supplied sterile and packaged in 20ml polycycloolefin syringes with a standard 7ml fill volume across the range. Available as 40µm, 75µm and 100µm microsphere diameter sizes, the ONCOZENE™ syringes are available with 2ml or 3ml microsphere volume per syringe. The product configurations are shown in the Table below.

Product REF Codes		***Volume of ONCOZENE™ Microspheres per syringe***	
		2ml microspheres	3ml microspheres
ONCOZENE™ Microsphere diameter	40 µm ±10 µm	10420-US1	10430-US1
	75 µm ±15 µm	10720-US1	10730-US1
	100 µm ±25 µm	11020-US1	11020-US1

5. Similarities and Differences to Predicate device

The intended use of ONCOZENE™ Microspheres and the predicate are equivalent. ONCOZENE™ Microspheres and the predicate device have the same design, specifications, fundamental scientific technology, and packaging.

The pH range of ONCOZENE™ Microspheres is more tightly controlled than the predicate but within the existing specification cleared for the predicate. Minor process changes have been made to achieve the tighter control of the pH range.

The predicate device is available in 1ml and 2ml microsphere volume per syringe. ONCOZENE™ Microspheres are available in 2ml and 3ml microsphere volume per syringe.

The predicate device is available sizes 40µm, 75µm, 100µm, 250µm, 400µm, 500µm, 700µm, and 900µm. ONCOZENE™ Microspheres are available in sizes 40µm, 75µm, and 100µm.

6. Summary of Technological Characteristics

Comparison between predicate (Embozene®) and ONCOZENE™Microspheres

Point of Comparison	Predicate	ONCOZENE™
Chemical composition	unchanged	
Osmolarity of transport solution	unchanged	
pH of transport solution	pH of transport solution is tighter for ONCOZENE than predicate but within existing specification for cleared predicate	
Size Range	40 ± 10 µm 75 ± 15 µm 100 ± 25 µm 250 ± 50 µm 400 ± 50 µm 500 ±50 µm 700 ± 50 µm 900 ± 75 µm	40 ± 10 µm 75 ± 15 µm 100 ± 25 µm
Color Code	Color or opaque	Opaque
Sterility	Pyrogen-free, sterile	Pyrogen-free, sterile
Packaging	Syringe or vial	Syringe
Syringe total fill volume	7ml	7ml
Microsphere volume per syringe	1 or 2 ml	2 or 3 ml
Shelf life	unchanged	
Indication for Use	unchanged	

7. Summary of In-Vitro Testing

The ONCOZENE™ Microspheres are a variant within the existing specification cleared for the predicate device. The minor changes made to the manufacturing processes to achieve tightened control of pH have not led to additional testing requirements.

8. Summary of Clinical Experience

The clinical evaluation included in the 510(k) reviews experience over the last ten years with Transrterial Embolization (TAE) using various embolic agents to physically occlude vessels to restrict blood flow. The evaluation looks at 1029 abstracts from the PubMed search including the predicate device and other embolic devices and reviews CeloNova's adverse event data resulting from in excess of 70,000 units distributed worldwide.

The overall review of the scientific literature and post market surveillance, indicate that embolization of tumors with small (40 µm and 100 µm) microspheres (Embozene® Microspheres) remain safe and effective for the treatment of hypervascularized tumors and arteriovenous malformations. Therefore, it could be concluded that the benefits of TAE with Embozene microspheres family including the

ONCOZENE™ Microspheres for the treatment of hypervascular tumors and arteriovenous malformations outweigh the potential risk when used within their labeled application.

9. Summary

ONCOZENE™ Microspheres are essentially equivalent to the predicate device Embozene Microspheres (K073417) but with a tighter controlled pH range (within the existing cleared specification). ONCOZENE™ Microspheres and the predicate device have the same indications for use, design, specifications, fundamental scientific technology, and packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2013

CeloNova Biosciences, Inc.
C/O Nicole C. Barber
18615 Tuscany Stone
Suite 100
San Antonio, Texas 78258

Re: K130307
Trade/Device Name: ONCOZENE™ Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: February 6, 2013
Received: February 7, 2013

Dear Ms. Barber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K130307

Device Name **Vascular Embolization Device**

Indications for Use **ONCOZENE™ Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations.**

Prescription Use X AND/ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner